



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/498,704	02/07/00	USTER	P 5325-0162.30

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EXAMINER

KISHORE, G

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/498,704

Applicant(s)

Uster

Examiner
Gollamudi S. Kishore, Ph.D

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1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 8
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claims included in the prosecution are 1-30.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marin (5,213,804) in combination with Mori (Cancer Chemther Pharmacol, 1995) of record, or vice versa.

Martin discloses a liposome compositions containing a phospholipid, 1-20 mol. % of a amphipathic lipid derivatized with PEG. The composition is for localizing an imaging or anti-tumor agent for therapeutic and diagnostic purposes (note the abstract, col. 1, line 34 et seq., Examples and claims).

What is lacking in Martin is the use of a radiosensitizer as the active agent

Mori while disclosing liposomes containing dipalmitoyl-5-fluoro-2-deoxyuridine teaches that treatment of lung metastasis bearing mice with the this composition resulted in

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significant increase in the median survival time of treated mice as compared to control mice (note the abstract and Materials and Methods).

What is lacking in Mori is the inclusion of lipid derivatized PEG.

The use of the radio sensitizer as the anti-tumor agent in the compositions of Martin would have been obvious to one of ordinary skill in the art because of its effectiveness shown by Mori. Alternately to use the lipid derivatized polymer in the liposomal compositions of Mori would have been obvious to one of ordinary skill in the art because of the increase in the blood circulation time of the liposomes as shown by Martin (note col. 14). Although Mori does not teach other halogen derivatives of deoxyuridine, in the absence of showing otherwise, it is deemed obvious to one of ordinary skill in the art to use halogens other than fluorine taught by Mori with a reasonable expectation of obtaining at least similar results.

3. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marin (5,213,804) in combination with Mori (Cancer Chemther Pharmacol, 1995) of record, or vice versa as set forth above, further in view of Kassis (5,077,034) of record.

As pointed out above, Mori does not teach iodine derivatives of deoxyuridine as the radiosensitizer. One of ordinary skill in the art would be motivated to use halogens other than fluorine taught by Mori with a reasonable expectation of obtaining at least similar results since Kassis teaches that the halogen derivatives of deoxyuridine, iodo-deoxyuridine

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derivative in particular is effective in the treatment and diagnosis of tumors (note the abstract, Examples and claims).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

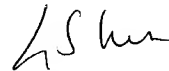
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 24, 2001